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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,682	02/10/2004	Rodolfo A. Morales	578492000510	3785

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MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER
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RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,682	<b>Applicant(s)</b> MORALES ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/1/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/27/08 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (U.S. Patent No. 5984933).

Claim 37: Yoon teaches a device for applying at least one clip to annular tissue of a heart valve (capable of being used to clip annular tissue of a heart) the device comprising; a shaft having a proximal end and a distal end (Fig. 48); at least one clip (2240) housed within a portion of the shaft and coupled to a tether (Figs. 44 and 48), wherein the at least one clip is configured to penetrate tissue (2241) upon release from the shaft (the examiner interprets the word upon according to the definition "immediately or very soon after", the device is capable of penetrating tissue very soon after being

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released), and wherein at least a portion of the at least one clip is deformable (attaching clip 2241 and 2239); and at least one actuator (2460) at or near the proximal end of the shaft for causing the device to advance the at least one clip from the shaft (Fig. 49).

Claims 38-40: Yoon teaches the device further comprises a clip crimping member (distal portion of 2440, Fig. 28), a plurality of clips (Fig. 48), each plurality of clips is couple to the tether (Fig. 48).

Claim 41: Yoon teaches at least one clip is T-shaped (see Fig. 44, if 2241 plane is shown, a T is formed out of 2240 and 2241)

Claims 42 and 43: Yoon teaches each of the plurality of clips includes two eyelets (2228), and the tether (2218a and 2218) has parallel segments passing through both eyelets of each clip (Fig. 44).

Claim 44: Yoon teaches a system for applying at least one clip to annular tissue of a heart valve, comprising: the device as claimed above in claim 37; and a stabilization device to capture and immobilize the annular tissue relative to the remainder of the heart (2232, Fig. 44, this inner face of the clip immobilizes the tissue).

Claims 45,46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933), as applied to claim 37 above, in view of Crowley (U.S. Patent No. 5524630).

Regarding claim 45 and 46 Yoon discloses the claimed invention except for a visualization device adapted to directly view a valve annulus in a heart chamber and a visualization device comprising an ultrasonic imaging transducer. However, Crowley teaches a visualization device adapted to directly view a valve annulus in a heart chamber (Fig. 30) and a visualization device comprising an ultrasonic imaging transducer (Fig. 3 and 4).

It would have been obvious to one of ordinary skill in the art to include a visualization device at the end of the claimed invention to insure proper installation of the clips during surgery.

Regarding claim 48 Yoon discloses the claimed invention except for a transparent element comprising a transparent balloon inflatable with a transparent inflation medium, however Crowley teaches a transparent balloon inflatable with a transparent inflation medium (col.4 ll.35, col. 17 ll. 6).

It would have been obvious to one of ordinary skill in the art to include a balloon at the end of the element to occlude blood flow, as this is common within the art.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933) and Crowley (U.S. Patent No. 5524630) as applied to claim 45 above, further in view of Johnson (5766240).

Regarding claim 47 Yoon discloses the claimed invention except for an optical viewing element, however Johnson discloses an optical viewing element (col. 15 ll.44) disposed in a transparent element (col. 5 ll. 11).

It would have been obvious to one of ordinary skill in the art to include an optical viewing element to insure proper installation of the clips during surgery.

### ***Response to Arguments***

Applicant's arguments filed 5/27/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The device of Yoon does not have the newly amended limitations including "clip is configured to penetrate tissue upon release from the shaft"

The examiners position is the device of Yoon teaches the structural limitations of the claims and is capable of being used as defined in the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773